

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 23 FEB 2006  
WIPO PCT

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|---|--|--|
| Applicant's or agent's file reference<br>BCS 04-5004 PCT  | <b>FOR FURTHER ACTION</b>                                |  |
|   | See Form PCT/IPEA/416                                    |  |
| International application No.<br>PCT/EP2005/002450  | International filing date (day/month/year)<br>04.03.2005 | Priority date (day/month/year)<br>05.03.2004 |
| International Patent Classification (IPC) or national classification and IPC<br>C12N15/82, C12N9/12, C07K16/40, C12N1/21, C12N5/10, C12N15/01, C12N15/11, C12N15/54, A01H5/00 |  |  |
| Applicant<br>BAYER CROPSCIENCE GMBH et al.  |  |  |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a.  *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:
    - sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b.  *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
  - Box No. I Basis of the opinion
  - Box No. II Priority
  - Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - Box No. IV Lack of unity of invention
  - Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - Box No. VI Certain documents cited
  - Box No. VII Certain defects in the international application
  - Box No. VIII Certain observations on the international application

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|--|---|
| Date of submission of the demand<br>21.12.2005   | Date of completion of this report<br>22.02.2006                     |
| Name and mailing address of the international preliminary examining authority:<br><br><br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized Officer<br><br>Kurz, B<br>Telephone No. +49 89 2399-7319 |



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## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

### Description, Pages

1-107 as originally filed

### Sequence listings part of the description, Pages

1-23 as originally filed

### Claims, Numbers

1-28 as originally filed

### Drawings, Sheets

1/6-6/6 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
  - the entire international application,
  - claims Nos. 1-28 (all partially)  
because:
    - the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
    - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-28 are so unclear that no meaningful opinion could be formed (*specify*):  
**see separate sheet**
  - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
  - no international search report has been established for the said claims Nos.
  - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

|                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
  - the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
  - See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |             |                       |
|-------------------------------|-------------|-----------------------|
| Novelty (N)                   | Yes: Claims | 3,8,16-19,21-24,26,28 |
|                               | No: Claims  | 1,2,4-7,9-15,20,25,27 |
| Inventive step (IS)           | Yes: Claims | -                     |
|                               | No: Claims  | 1-28                  |
| Industrial applicability (IA) | Yes: Claims | 1-28                  |
|                               | No: Claims  | -                     |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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**Supplemental Box relating to Sequence Listing**

**Continuation of Box I, item 2:**

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
  - a. type of material:  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material:  
 in written format  
 in computer readable form
  - c. time of filing/furnishing:  
 contained in the international application as filed  
 filed together with the international application in computer readable form  
 furnished subsequently to this Authority for the purposes of search and/or examination  
 received by this Authority as an amendment on
2.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

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**Re Item II**

**Priority**

Priority has been checked and has been found to be validly claimed for the present set of claims. If amended claims are filed, priority of the newly claimed subject-matter has to be assessed again.

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 1, 14, and 16 pertain to the activity of OK1. OK1 is an arbitrary designation without any meaning to a technically skilled person. In the absence of a reference to a particular sequence, claim 1 is considered to lack clarity according to Article 6 PCT to such an extent that the scope of the claim is totally unlimited (see Item VIII, below). Search has therefore been limited to those sequences which are disclosed in the application, i.e. Seq. ID Nos. 1-4, 10 and 11. The same applies to claims 2-13, 15, and 17-19 which directly or indirectly depend on claims 1, 14, and 16.

Claims 20-28 pertain to modified and derived starches and methods to produce them. In the absence of any technical features of the claimed starch, claims 20-28 lack clarity (Article 6 PCT) to such an extent that a meaningful search and examination is not possible (see Item VIII, below). Search was therefore limited to transgenic or mutant plants having altered activities of Seq. ID Nos. 1-4, 10, and 11 or having a starch excess phenotype and to the starch produced by such plants.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The present application pertains to the reduction of the activity of phosphoglucan, water dikinase (OK1, PWD) in plants and to the starch produced by such plants.

Reference is made to the following documents:

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International application No.  
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D1: ALONSO J M ET AL: "Genome-wide insertional mutagenesis of *Arabidopsis thaliana*" 1 August 2003 (2003-08-01), SCIENCE, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE,, US, PAGE(S) 653-657 , XP002300984 ISSN: 0036-8075

D2: MAHMOUD Z. SITOHY ET AL.: "Optimizing the conditions for starch dry phosphorylation with sodium mono- and dihydhydrogen orthophosphate under heat and vacuum" STARCH/STÄRKE, vol. 52, no. 4, June 2000 (2000-06), pages 95-100, XP002349827

D3: YU T-S ET AL: "The *Arabidopsis sex1* mutant is defective in the R1 protein, a general regulator of starch degradation in plants, and not in the chloroplast hexose transporter" PLANT CELL, AMERICAN SOCIETY OF PLANT PHYSIOLOGISTS, ROCKVILLE, MD, US, vol. 13, no. 8, August 2001 (2001-08), pages 1907-1918, XP002252059 ISSN: 1040-4651 cited in the application

D4: BLENNOW A ET AL: "Starch phosphorylation: A new front line in starch research" TRENDS IN PLANT SCIENCE, ELSEVIER SCIENCE, OXFORD, GB, vol. 7, no. 10, October 2002 (2002-10), pages 445-450, XP002339248 ISSN: 1360-1385

1. Claim 1 is formulated such that naturally occurring mutant plants are encompassed in the claim. Therefore claims 1, 5-11, 20 and 25 lack novelty as required by Article 33(2) PCT.
2. Document D1 discloses the T-DNA tagging of virtually all genes present in the *Arabidopsis* genome. Several of these tags are located in the gene encoding PWD. One of these T-DNA tagged lines is disclosed as SALK\_110814, represented by the database accession number BZ665165. With respect to this T-DNA tagged line, present claims 1, 2, 4-6, 7, 9-15, 20 and 25 lack novelty (Article 33(2) PCT). As RNAi technology, antisense constructs, co-suppression, ribozymes and transposons are all known methods to reduce the expression level of a particular protein or enzyme, these methods represent alternatives to T-DNA tagged lines. Consequently, claims 3, 8, and 16-19 lack inventive activity as required by Article 33(3) PCT. The extraction of starch from plants and the chemical treatment of starch are routine methods rendering claims 21-24 and 26-28 not inventive (Article 33(3) PCT).
3. In the absence of technical features it is at present not apparent how the starch of claims 20-28 can be delimited from starch known in the art (cf D3). According to

the EPC, product-by-process claims are only allowable if the products as such fulfil the requirements of novelty and inventive step.

Claim 27 encompasses all types of starches with all types of chemical alterations so that e.g. starches produced according to D2 fall into the scope of the claim.

Claim 27 therefore lacks novelty (Article 33(2) PCT).

4. Documents D3 (page 1909, left column) and D4 (page 449, right column) disclose the existence of glucan, water dikinase homologues in *Arabidopsis*. The one on chromosome 5 was later identified as the PWD used in the present application. As the location on the chromosome was known and as reverse genetics have been proposed in D4, claims 16-19 are considered to lack inventive activity (Article 33(3) PCT). Concerning all other claims the disclosures of D3 and D4 at present are considered not enabling.

**Re Item VIII**

**Certain observations on the international application**

1. Claims 1, 14, and 16 pertain to the activity of OK1. OK1 is an arbitrary designation without any meaning to a technically skilled person. In the absence of a reference to a particular sequence, claim 1 is considered to lack clarity according to Article 6 PCT and Rule 6.3 PCT to such an extent that the scope of the claim is totally unlimited.  
The IPEA is of the opinion that according to Article 6 and Rule 6.3 PCT the claims shall define the matter for which protection is sought in terms of technical features. (Poly)peptides, proteins, (oligo)nucleotides, genes etc. are considered to be chemical products which must be clearly and unambiguously characterized by their amino acid and/or nucleic acid sequences, i.e. by reference to their Seq ID No.
2. Claim 1 is formulated as a result to be achieved and lacks technical features. For reasons of clarity (Article 6 PCT) claim 1 should be amended accordingly.
3. For reasons of clarity (Article 6 PCT) terms in brackets should be avoided. Claims 4, 9, 14, and 16 should be reformulated.
4. Claims 4f) and 14f) pertain to antibodies. Such antibodies can only be accepted if binding specifically to a particular sequence. In the present case other sequences

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encoding dikinase enzymes sharing common motifs are known in the art (cf D3). Antibodies directed to such motifs may cross-react, thus rendering claims 4 and 14 not novel or inventive (Article 33(2) and (3) PCT).

5. Claim 7 lacks clarity (Article 6 PCT) as the term "starch-storing plant" does not have a generally accepted meaning. In the broadest sense all plants store starch at least transiently.
6. Claims 20-28 pertain to modified and derived starches and to methods to produce them. In the absence of any technical features of the claimed starch, claims 20-28 lack clarity (Article 6 PCT) to such an extent that a meaningful search and examination is not possible. At present, the claimed starch is characterized by the method by which it can be obtained, i.e. by reducing the activity of a phosphoglucan, water dikinase in plants. In the PCT contracting states no unified criteria exist concerning this type of claims. Before the EPO such claims, defined in terms of a process of manufacture are only admissible if the product as such fulfils the requirements of patentability and if the wording of the claim is "product X obtainable by the process Y". Furthermore, such claims are only considered allowable if the product cannot be characterized by technical features, which is not the case here.
7. Claim 27 not only lacks clarity, but also support from the description (Article 5 PCT). In the absence of any examples the claimed starch is not characterized in any way. The claim encompasses all starches, and in particular all chemically altered starches which renders claim 27 not novel (see Item V, above).
8. The subject-matter of some of claims 20-28 seems to be redundant. The number of claims should therefore be adapted (Rule 6.1 (a) PCT).